Conference of Radiation Control Program Directors, Inc.

10th Annual NATIONAL CONFERENCE ON RADIATION CONTROL

A Decade of Progress

April 30 - May 4, 1978
Harrisburg, Pennsylvania

Published by

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
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Cosponsored by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

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ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation Programs

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U.S. NUCLEAR REGULATORY COMMISSION

and

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland, 20857

FOREWORD

The Bureau of Radiological Health conducts a national program to limit man's exposure to ionizing and nonionizing radiations. To this end, the Bureau (1) develops criteria and recommends standards for safe limits of radiation exposure, (2) develops methods and techniques for controlling radiation exposure, (3) plans and conducts research to determine health effects of radiation exposure, (4) provides technical assistance to agencies responsible for radiological health control programs, and (5) conducts an electronic product and medical device radiation control program to protect the public health and safety.

The Bureau publishes its findings in appropriate scientific journals and technical report and note series prepared by Bureau divisions and offices. Under a memorandum of agreement between the World Health Organization and the Department of Health, Education, and Welfare, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations (Office of the Bureau Director)

WHO Collaborating Center for Training and General Tasks in Radiation Medicine (Division of Training and Medical Applications)

WHO Collaborating Center for Nuclear Medicine (Office of the Bureau Director)

As a WHO Collaborating Center, the Bureau makes available its technical reports and notes to participating WHO members.

Bureau publications provide an effective mechanism for disseminating results of intramural and contractor projects. The publications are distributed to State and local radiological health personnel, Bureau technical staff, Bureau advisory committee members, information services, industry, hospitals, laboratories, schools, the press, and other concerned individuals. These publications are for sale by the Government Printing Office and/or the National Technical Information Service.

Readers are encouraged to report errors or omissions to the Bureau. Your comments or requests for further information are also solicited.

John C. Villforth
Director
Bureau of Radiological Health

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Moris Shore
Director
Division of Biological Effects
Bureau of Radiological Health, FDA

INTRODUCTION

During the course of a microwave oven compliance action, which is a matter of public record, the following statement was made on behalf of the oven manufacturer:

> "A recent publication of the International Microwave Power Institute. . .describes the safety standards for microwave emissions promulgated by the Occupational Safety and Health Administration (OSHA) and the American National Standards Institute (ANSI). Both standards incorporate the notion of 'Radiation Protection Guide' of 10 mW/cm^2. By their terms, they allow continuous, whole-body exposure to this level of radiation. . . The OSHA standard (29 CFR 1910.97) is particularly significant because the specified level represents a formal finding by the Secretary of Labor that '. . .No employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.' " (1)

The implication of safety drawn by the manufacturer should be viewed in the context that OSHA in fact adopted the ANSI standard, and did not independently develop a biological basis for the ANSI formulation which it adopted. Furthermore, to our knowledge neither USASI (United States of America Standards Institute) nor ANSI (American National Standards Institute) provided a biological basis for the 10 mW/cm^2 standard they promulgated.

CHRONOLOGY and ESSENTIAL PROVISIONS of the ANSI-USASI STANDARD

On November 9, 1966, the United States of America Standards Institute promulgated a standard entitled "USA Standard, Safety Level of Electromagnetic Radiation with Respect to Personnel." This was an occupational exposure guide which specified the following (2):

> "For normal environmental conditions and for incident electromagnetic energy of frequencies from 10 MHz to 100 GHz, the radiation protection guide is 10 mW/cm^2 (milliwatt per square centimeter) as averaged over any possible 0.1-hour period."

The standard cautioned:

> "People who suffer from circulatory difficulties and some other ailments are more vulnerable. . . The guide numbers are appropriate for moderate environments. . . Under conditions of moderate to severe heat stress the guide number given should be appropriately reduced. . . These values are based on an evaluation of presently available knowledge and with due consideration of tolerable rise in tissue temperature. . . .Radiation characterized by a power level tenfold smaller will not result in any noticeable effect on mankind. . . Radiation levels which are tenfold larger than recommended are certainly dangerous. . . These formulated recommendations pertain to both whole body irradiation and partial body irradiation. Partial body irradiation must be included since it has been shown that some parts of the human body (e.g., eyes, testicles) may be harmed if exposed to incident radiation levels significantly in excess of the recommended levels."

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environment, of an uncontrolled population of mixed sensitivity to radiation insult. These were considerations incorporated in the letters of EPA and BRH representatives who counseled against reaffirmation of the 10 mW/cm^2 "safety level" by ANSI. (Preliminary information suggests that a recommendation of 5 μW/cm^2 is being considered in the USSR for promulgation as a general population exposure standard in the microwave region.)

USASI and ANSI recognized a number of these factors in the text of their undocumented standards. However, they failed to provide specific guidance to deal with environmental factors or the problem that "people who suffer from circulatory and certain other ailments are more vulnerable." The above statement was made by both USASI and ANSI.

A number of reviews and compilations that include Eastern European literature on microwave biological effects exist (5-14).

ORIGINS of the 10 MILLIWATT PER SQUARE CENTIMETER "SAFE EXPOSURE LEVEL"

In 1959, Frank Leary, Associate Editor of Electronics, stated (15):

> "Until five years ago (i.e., 1954), understanding of the effects of R-F energy on living tissue was limited to a handful of experiments performed on rats and dogs, and a small body of experience with microwave diathermy. . . Within the last two years (i.e., 1957), a massive research program has attempted to enlarge our understanding of the biological effects of microwave exposure. The program is sponsored by the Defense Department, and coordinated at. . .Cape Canaveral by Colonel George M. Knauf. . ."

The Defense Department program to which Mr. Leary made reference was the Tri-Service Program with biomedical research responsibility assigned to the Rome Air Development Center, Griffis AFB, New York. Dr. Knauf was designated coordinator for the program. Dr. Sol Michaelson described the program as follows (16):

> "The Tri-Service Program included investigation of effects of exposure in the frequency spectrum from 200 through 24,500 MHz. . .
>
> "Annual Tri-Service Conferences were initiated in 1956 by RADC as the means for reporting to the military services.
>
> "In an effort to establish a safe exposure level to microwaves many variables were considered, . . . Sufficient factual data were not available to determine the 'safe' exposure level for each frequency throughout the spectrum; . . . Possibly some cases of reported damage were no doubt caused by power densities of approximately 0.1 W/cm^2. . . A safety factor of 10 was decided upon, and a safe level of 0.01 W/cm^2 was established (78)."

Thus, the Tri-Service Program was described as a substantial effort which began in 1957 and culminated in the establishment of a scientifically based "safe level" of 10 mW/cm^2 in 1966-67. (Michaelson's reference 78 is to the U.S. Air Force, "Electromagnetic radiation hazards, T.O. 31Z-10-4, 1966, rev. 1967).

In 1957, Dr. Knauf stated:

> "A maximum allowable ambient level of .01 W/cm^2 has been arbitrarily established and the field notified. . . No point in time has been considered valid in the absence of data on effects of chronic exposure." (17, page 90).
>
> "Our hand has been to some degree forced in the establishment of this safe exposure level of .01 Watt/cm^2." (18, page 44).

The following two Air Force notifications established a "hazardous level of microwave radiation of 10 milliwatts/cm^2 or greater over the entire microwave spectrum" (19):

1. Microwave Radiation Hazards
   Urgent Action Tech. Order 31-1-511
   Rome Air Force Depot, Griffis AFB, N.Y.
   17 June 1957.

2. Industrial Hazards
   RADC Regulation N.R. 160-1, 31 May 1957
   Headquarters, Rome Air Development Center
   Griffis AFB, N.Y.

Thus it would appear that 10 mW/cm^2 was established as a "safe exposure level" by the Air Force in 1957--"arbitrarily" in the words of Dr. Knauf.

It is significant to note that this action was taken in 1957, the year in which the Tri-Service Program was initiated.

DID other than BIOLOGICAL RISK BASES "FORCE" the "ARBITRARY ESTABLISHMENT" of the 10 MILLIWATT PER SQUARE CENTIMETER "SAFE" EXPOSURE LEVEL?

If the 10 mW/cm^2 "safe" exposure level was not scientifically based but rather arbitrarily established, can we obtain any insight into the factors that forced its selection? Let us examine again statements made by Dr. Knauf.

In 1957 Dr. Knauf stated (18):

> "Gentlemen, there is nothing about the establishment of a research program or the publication of precautionary instructions which in themselves legislate against the application of a little common sense. Our hand has been to some degree forced in the establishment of this safe exposure level of .01 watt/cm^2. Some months after we arrived at a decision to establish .01 watt/cm^2 as the Air Force safe exposure level, we received a report from a leading industrial laboratory in which it was proposed to establish the safe exposure at 1 milliwatt/cm^2. We did not agree with this level nor did we feel that we had sufficient data to contest this report. In the meantime, the same contractor in connection with another Air Force contract has written to say that in their opinion, .01 watt/cm^2 constitutes a completely safe exposure level for personnel. I do not know that the 1 milliwatt proposal has been rescinded but do believe the parent company has had a change of heart. More recently, another leader in the field of microwave research has sponsored a level of .1 of a milliwatt/cm^2 as being the safe exposure level for personnel. They further complicate the picture by saying that when the level exceeds .1 of a milliwatt and lies between .1 of a milliwatt and 1 milliwatt, personnel should be restricted from working in the area in excess of 1/2 hour in any 24 hour period. We can not find justification for this stand anywhere in the literature. In a recent conference with the engineer who wrote the report and the medical director of the company concerned, we got the impression that this level was sponsored in keeping with a company policy to take no chances. We are of the opinion that when they establish such a level they are indeed taking no chances." (page 44).

Thus, while Dr. Knauf agreed to the need for an "arbitrary safe exposure of 10 mW/cm^2," he resisted vigorously any suggestion that a limit of less than 10 mW/cm^2 be considered.

Frank Leary shed additional light on divergent views on safe limits in 1959 when he stated (15):

> "Army training areas have certain characteristics in common with industry testing grounds. The army has established these criteria for its training areas:. . . Sets are separated by distances that reduce searchlighting exposures to less than 0.01 w/cm^2. . .

Rest areas are provided where power densities are 0.001 w/cm^2 or less. . . General Electric has been observing these safety standards since June 1, 1954. . . Prevent exposure to direct beams, especially of the eyes. . . Limit direct or reflected intensity in all areas to which people require access to 0.001 W/cm^2." (page 52).

Thus, according to Leary, the army and the General Electric Company had some reservations about 10 mW/cm^2 as an arbitrary safe limit. Apparently, the Bell Telephone Laboratories also dissented.

Dr. Mumford provided the following table as a summary of Bell Telephone Laboratories recommendations in 1961 (20):

Table II

Summary of Bell System Recommendations

L. For the time being, microwave exposure limits may be classified as follows:

Average Power Density mW/cm^2	Classification
Above 10	Potentially hazardous
Between 1 and 10	Safe for incidental or occasional exposure
Below 1	Safe for indefinitely prolonged exposure or permanent assignment."

Dr. Knauf also noted (21):

"Because of the peculiar configuration of this equipment, it will be necessary for certain technical personnel to spend varying periods of time in areas where the ambient power level will exceed .01 W/cm^2. . . It is sufficient to say that the power of this proposed equipment, is much greater than anything we have dealt with before." (page 7)

Thus we see in the overall pattern the following: A safe exposure level of microwave exposure was arbitrarily established--no dissent from the arbitrary safe standard was tolerated--in a largely thermal (i.e., high exposure level) microwave research program sponsors preferred to speak about "effects" rather than "hazards"--a requirement for exposure to levels in excess of 10 mW/cm^2 was specified--the arbitrarily established safe level of 10 mW/cm^2 in 1957 was followed by the promulgation in 1966 and reaffirmation in 1974 (by USASI and ANSI respectively) of a 10 mW/cm^2 safety level standard, which now incorporated a provision for permissible exposure to levels in excess of 10 mW/cm^2.

The record provides a basis for concern that the "safety level" of 10 mW/cm^2, and the averaging provisions that permit exposure to levels in excess of 10 mW/cm^2 may represent a directed verdict rather than the culmination of objective and unbiased scientific judgment.

There is a need to comprehensively evaluate existing knowledge of microwave health effects. Such an overview can serve as the basis for the development of consistent national recommendations for permissible general population and occupational human exposure, as well as permissible microwave leakage from electronic products. It should be noted that such overviews are currently being planned or developed by a number of national and international agencies including Food and Drug Administration, Environmental Protection Agency, Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, and the World Health Organization. Significant gaps in information may be identified that will require further attention.

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other 8 members representing two organizations of State and local civil defense organizations. The activities of this Committee have thus far somewhat paralleled those of our Task Force No. 12.

Task Force No. 14, Quality Assurance, has completed a draft of a manual on quality assurance in the use of x rays in the healing arts. I commend Chairman Hardin and the members of this Task Force for the excellent report submitted.

Task Force No. 15, Mammography, has devoted its attention to methods of reducing breast exposure from mammography while retaining high-quality radiographs and to the review of the quality assurance program known as BENT (Breast Exposure: Nationwide Trends).

Task Force No. 16, Radiation Measurements, has nearly completed a first draft of a manual containing charts of the parameters of all of the radiation measurements procedures used (or required) in radiation control; this has been a monumental task and has required a large amount of work from this Task Force in a comparatively short time.

Task Force No. 17, Personnel Dosimetry, has fulfilled its charge in the past year by continuing to monitor developments in the area of personnel dosimetry.

Task Force No. 18, Efficacy of Application of Radiation in the Healing Arts is newly established. Its first project will be to define efficacy, which will be no easy task, in light of the diverse views on this subject.

The Training and Communications Task Force has been active in determining means by which the training needs of State and local personnel can be met. In particular, the Task Force has been developing recommendations on methods of training using the National Radiation Control TV Network inaugurated in September of 1977.

The Task Force on Suggested State Regulations for Lasers has very recently completed a draft of Model State Laser Regulations.

With apologies for brevity, this completes the report on the current activities and accomplishments of the Conference Task Forces. I thank the Chairmen and members of these Task Forces for their efforts so fully given in the pursuit of these tasks.

Another accomplishment of the Conference is the Sponsorship of this 10th Annual National Conference on Radiation Control: that may be a statement of the obvious, but I feel that the point should be noted. The planning and preparation for this National Conference began over a year ago and required a great amount of effort and thought; of course, this National Conference would not have been possible without the assistance of our Federal colleagues and others, such as invited speakers, from outside the radiation control field. We are grateful for their assistance in this endeavor. I believe that we have an excellent program assembled for this National Conference as a culmination of the many who have contributed of their time and effort.

The Executive Board of the Conference has held four 2-day meetings in the past 10 months. Without making any attempt to be specific, let me simply report that the Board has concerned itself with the operation of the Conference on behalf of and for the members of the Conference.

Next, I will turn to the subject of current issues facing the Conference. Let me state clearly that the selection of these issues is my own. The order in which the following issues are placed is arbitrary and is not intended to indicate a system of priority.

Training is an issue currently facing the Conference as it has in the past. As I have stated in the past, I continue to feel that training is an essential element in the best utilization of new personnel entering this field and in the provision of new skills and knowledge to more experienced personnel in regard to new technologies and uses of radiation. Because of my

To illustrate the difficulties facing a practicing physician, let us consider a family physician concerned with the proper treatment of women in whom preoperatively the possibility of breast cancer is relatively high. The disease may be early and minimal or relatively advanced. The question asked is as follows: Should each of these patients have a preoperative bone scan?

Recently, O'Connell et al. (2) reported from the Mayo Clinic that preoperative radionuclide bone scanning in suspected primary breast carcinoma found only one positive preoperative scan in 85 patients prior to surgery. There were 22 percent of equivocal scans in this group, none of which proved to be malignant when reviewed, and in three cases biopsied. Hence, at Mayo Clinic, one would judge this test to be unnecessary.

If, however, one looks further one finds 3 of 35 patients with positive bone scans and negative x rays preoperatively and all subsequently died of metastatic disease (3). Gerber et al. (4), in studying 122 women with breast cancer, found only 7 (6 percent) with positive findings preoperatively, but 12 patients subsequently developed positive scans and clinical evidence of metastasis.

Citrin et al. (5) found 11 patients with positive scans in a group of 75 patients and normal x rays preoperatively, and most of them became abnormal subsequently. Thirteen additional patients with normal preoperative scans converted to abnormal scans subsequently. Fifty-one of the 75 patients (68 percent) remained normal for a mean period of 16 months.

These several studies simply demonstrate the great variability in degrees of illness between different institutions. A study which is of relatively little value at Mayo Clinic and of moderate value at the National Naval Medical Center seems to be of greater value at general hospitals in Glasgow and Philadelphia. Thus, when one attempts to develop rules or indications for a given study, these become a function of the interest and specialization within medical centers and community hospitals.

Other physicians who have evaluated bone scans in women with early stages of breast cancer find the yield of positive lesions to be so low as to make the procedure not useful unless the patient experiences bone pain or if the staging is questionable. Stage II and Stage III lesions (patients with large tumors and enlarged axillary lymph nodes) show a much higher yield of positive diagnoses and in such circumstances the bone scan is more efficacious. Actually physicians differ somewhat in their judgments concerning the usefulness of preoperative scans even in Stage I and II lesions. Some regard a baseline scan as being helpful since many other non-malignant conditions can demonstrate localized areas of increased uptake. The majority of writers on this subject do not recommend bone scanning as a routine procedure but the decision should be made by the physicians and not the regulators or insurance carriers.

RISK BENEFIT

The use of bone scans in the preoperative workup of a patient suspected of breast cancer illustrates the dilemma of the referring physician whose responsibility is a priori to judge that the benefit, say of a bone scan in the circumstances described above, is expected to exceed the risk before ordering the scan and prior to surgery. This procedure can be expected to deliver about 0.03 rads per millicurie of Technetium-99m to the bone marrow of a 50-year-old woman and increase her cancer risk by less than 1 percent, based on the linear no-threshold model.

In order to attack this question Saenger et al. (6) queried a group of urologists concerning a radiological procedure and developed a non-dimenstional ratio of benefit to risk using the same MICRO technique as we plan to use in this study and has been used in the American College of Radiology study. We assigned by judgment some arbitrary values to the LLR as shown in Table 2.

RADIATION BENEFIT/RISK in NUCLEAR MEDICINE

Robert W. McConnell, M.D.
Nuclear Radiology Department
University of Texas Medical School

In view of the plethora of scholarly articles in this seemingly limited field it is perhaps presumptious of me to attempt to add this small contribution. Especially so since the prior disertations have been conducted by such eminent workers and their dissertations so lucid and complete.

I had an opportunity to review the risks, benefits, facts, issues, or opinions concerning the medical nature of radiation from several of your previous publications; those from the 1975 and 1976 conferences of Radiation Control Program Directors. Thus, I have availed myself of comments by Drs. McClenahan, Nadar, Wise, Brown, and others. I noted that in many of the papers that I read, a certain amount of heat, and occasionally heat and a little light, is cast on the situation.

You have asked for my opinion about the risks and benefits of nuclear medicine procedures relating them, in addition, to other imaging modalities in which ionizing radiation is utilized. Nuclear medicine can be separated into two arbitrary divisions. Those in which radioactive drug is categorically administered to a patient are called "in vivo procedures," made up principally of dynamic or static energy in procedures and commonly performed in radiology departments in a division called "nuclear radiology." "In vitro procedures" are those studies done in a laboratory environment commonly in the pathology department. I will confine my remarks to in vivo procedures and attempt to give you my understanding of the present state of the radiological art.

In order to put this in proper perspective, there are some basic back-to-the-drawing-board issues that need discussion. First, there is no country in the world whose people value life itself as much as you Americans. When to pull the plug on life sustaining equipment for patients who exibit obvious signs of cerebral death has become a legal rather than a medical decision. Secondly, there is no country in the world which has attempted to change its environment as much as have Americans. The kinds of environment that we attempt to air condition is only one example. All of these things and many others play a particular role in the attitudes that Americans have for what is somewhat cynically called happiness, creature comfort, security, or the quality of life. One can draw inferences from such articles as that by A. Comfort, writing in the American Geriatrics Society Journal, "Most people can and should expect to have sex long after they no longer wish to ride bicycles." One cannot escape from these socioeconomic philosophies if one is to properly access the practice of medicine today.

In his article, "The Quality of Survival and Response to Treatment," W. Bradford Patterson discussed the quality of that response in this fashion. He held that if quality is to have a real value, certain components should be considered. These must include the health of the patient; for instance, the prospect of cure versus failure. Secondly, function; the ability of the patient to work and the quality of that performance. Thirdly, comfort; the freedom from pain and limitations through activity. Fourth, emotional response, self acceptance, anxiety about the future, and social adjustments. Lastly, the economic phases; the impacts of the cost of living and the earning capacity of that individual. Needless to say, the prolongation of life without improving symptoms or function, or the cure that is worse than the disease, is not a worthwhile response. Those of us that work in a diagnostic speciality rather than a treatment speciality are constantly evaluated by our peers in other specialities. Worthwhileness--the benefit to the referring physician and thus to the patient--can perhaps be measured in patient response to the treatment instigated by the results of the